



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/629,613 | 07/30/2003 | Yoshihiro Abiko | ZU-414/CIP | 5531 |
| 35777 | 7590 | 03/13/2006 | EXAMINER | |
| SHERMAN & ASSOCIATES 415 NORTH ALFRED STREET ALEXANDRIA, VA 22314 | | | SHAW, AMANDA MARIE | |
| | | | ART UNIT | PAPER NUMBER |

1634

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,613

Applicant(s)

ABIKO ET AL.

Examiner

Amanda M. Shaw

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 3-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. The reply filed on 2/6/2006 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): the response does not include an election of a specific primer set and mutation with respect to group 2 {{applicant was asked to elect a specific primer set and specific mutation with regards to group 2}}. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

2. Acknowledgement is made of Applicant's election of Group II, claims 3-17, in the response filed February 6, 2006. However, the response fails to include an election of a specific primer and specific mutation, as required in the Office action of January 4, 2006. The response states that the requirement to elect a specific primer set and mutation is not proper because the requirement is being applied to members of a Markush group recited in a single claim. This argument has been fully considered but is not persuasive. In the instant application, restriction of the subject matter is proper because the claims have been presented in improper Markush format, as distinct nucleotides and mutations are improperly joined by the claims. Group II reads on patentably distinct inventions drawn to multiple nucleic acid sequences and multiple mutations. The claims encompass nucleic acids consisting of distinct nucleotide

sequences selected from the group consisting of SEQ ID NO: 1-8. Each nucleic acid consists of a different nucleotide sequence, has a different melting temperature, a different specificity of hybridization, and encodes for a protein having a different biological activity. For example, a nucleic acid comprising SEQ ID NO: 1 is chemically, structurally and functionally distinct from a nucleic acid comprising SEQ ID NO: 8. A search for a nucleic acid comprising SEQ ID NO: 1 would not be co-extensive with a search for a nucleic acid comprising SEQ ID NO: 8. Further, a finding that nucleic acid comprising SEQ ID NO: 1, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that a nucleic acid comprising SEQ ID NO: 8 is also novel and unobvious over the prior art. Similarly, a finding that a nucleic acid comprising SEQ ID NO: 1 is anticipated or obvious over the prior art would not necessarily extend to a finding that a nucleic acid comprising SEQ ID NO: 8 is also anticipated or obvious over the prior art. The same holds true for the mutations. The claims encompass several distinct mutations. Each mutation occurs at a different nucleotide position, has a different nucleotide substituted, and encodes for a different amino acid. For example, the mutation at nucleotide position -1035 is chemically, structurally and functionally distinct from a mutation at nucleotide position -1027. A search for the mutation at nucleotide position -1035 would not be co-extensive with a search for the mutation at nucleotide position -1027. Further, a finding that the mutation at nucleotide position -1035, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that the mutation at nucleotide position -1027 is also novel and unobvious over the prior art. Similarly, a finding that the mutation at nucleotide position -

1035 is anticipated or obvious over the prior art would not necessarily extend to a finding that the mutation at nucleotide position –1027 is also anticipated or obvious over the prior art.

Accordingly, the nucleotide sequences and mutations are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, applicant should elect one set of primers and one mutation to be examined.

3. Also please note that Claims 3, 12, and 15 are linking claims. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

As for now only the dependent claims that read on the elected primer set and mutation will be examined.

4. Applicant is advised that the response to this requirement to be complete must include an election of a primer set and a mutation to be examined even though the requirement is traversed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634
March 7, 2006


CARLA J. MYERS
PRIMARY EXAMINER